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08/253,212 06/02/94 REEVE

18N1/0110

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M 263GB910021  
EXAMINER

REARDON, T

ART UNIT PAPER NUMBER

16

1815  
DATE MAILED:

01/10/95

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 6/1/94, 10/14/94, 10/12/94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ✓ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.             | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.       |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/>   |

Part II SUMMARY OF ACTION

1. ☒ Claims 3, 9-10, 13, 15, 17, 21 are pending in the application.  
Of the above, claims 16 are withdrawn from consideration.
2. ☒ Claims 16 have been cancelled.
3. ☐ Claims are allowed.
4. ☒ Claims 3, 9-10, 13, 15, 17, 21 are rejected.
5. ☐ Claims are objected to.
6. ☐ Claims are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on 5/7/95. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on 5/7/95, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed 5/7/95, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received ☐ been filed in parent application, serial no.                     ; filed on                     .
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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1. Examiner acknowledges the amendment, response, instruction booklets of 10/4/94 and 10/17/94.

Claims 3, 9-10, 13-15, 17 and 21 are pending.

5 2. Claims 3, 13, 14, 17 and 21 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is fully enabling only for claims limited to the procedures demonstrated in Examples 1-3. The disclosure fails to enable all other possible precipitations from other biological fluids encompassed by the language of the claims. See M.P.E.P. §§ 706.03(n) and 706.03(z).

10

These examples show, apparently successfully, the present method applied to a variety of target substances: a sample of nucleic acid, a sample of nucleic acid with protein and a sample of phage. Each of these examples was performed on a clean, artificial mixture of the target substance and the qualitative results were stated.

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The remaining examples are speculative in nature as they appear to be laboratory protocols presented without even qualitative results.

20 The principle difference between the enabling examples and the non-enabling examples is in the phrases used to describe them. The enabled examples use phrases similar to "has been used" in describing the procedures. The non-enabled examples uses phrases similar to "can be used".

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This phrase is speculative and is not adequate to overcome the reasons given below for finding the disclosure non-enabling for all the separations encompassed by the language of the claims cited above.

5           The present disclosure is not adequate to enable the many biopolymer~~s~~, let alone non-biopolymer, encompassed by the present claim language. For instance, the isolation of nucleic acid from lysate or the isolation of blood cells from whole blood present far more challenging and impure mixtures than those demonstrated  
10 to date. These complex mixtures present physical and chemical interactions where the precipitation of one species in the presence of the large surface area of the present beads may well result in the precipitation of another rather than a separation of them. See, for instance, lines 30-35 of specification page 12  
15 where the precipitation of some species agglomerate (entrap) other species. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Applicant's arguments filed 10/4/94 have been fully considered but they are not deemed to be persuasive. The reasons for citing the lack of enablement is thoroughly described above.  
20 Contrary to the Applicants' contention, a mere protocol is insufficient to demonstrate enablement.

Applicant contends that one of skill would be able to perform the techniques of the claims. This is not well taken because one of skill must be able to conduct the present methods

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successfully without undue experimentation. In the face of the logical reasoning of non-enablement presented above, successful demonstration to overcome this burden is lacking.

Applicant again presents sales literature in an attempt to show that one of skill would have been able to conduct the presently claimed separations. This is not persuasive because no date of publication or indication of public availability has been given for these materials. Contrary to the Applicants assertion, date of publication is material. Without it examiner cannot assess if these represent the level of skill at the time of filing.

Further, there is no indication that the protocol in the sales literature actually achieves successful results. Finally, applicant should compare the date of public sale or use to the filing date.

3. Claims 3, 9-10, 13-15 and 17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Examiner recommends insertion of the phrase --containing nucleic acid-- after "solution" into line 2 of claim 13. Claim 13 is unclear in setting forth which solution is referred to in line 6.

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The following terms lack proper antecedent basis in the claims: "a solution" in line 3 of claim 13; "impure solution" in line 5 of claim 14; "suspended magnetically attractable particles" in lines 7-8 of claim 15.

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4. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Reardon, whose telephone number is (703) 308-3972. The examiner can normally be reached on Monday through Thursday from 8:00am until 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, may be reached on 703-308-4743. The fax phone number for Group 180 is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Timothy J. Reardon  
January 9, 1995

  
MICHAEL G. WITYSHYN  
SUPERVISORY PATENT EXAMINER  
GROUP 1800  
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